DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#13

AUG - 5 1996

Re: ULTANE™
Docket No. 95E-0302

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 4,250,334 filed by Baxter International, Inc. under 35 U.S.C. § 156. The patent claims the human drug product ULTANE™, New Drug Application (NDA) 20-478.

In the December 7, 1995, issue of the Federal Register (60 Fed. Reg. 62869), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before June 5, 1996, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

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DEPUTY ASSISTANT
COMMISSIONER FOR PATENTS

cc: Henry D. Coleman
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